

**REMARKS**

Claims 27, 29, 31-33, 35-40, 44, 48-52, 54, 56-64, 67 and 71-76 are currently pending in this application. Claims 27 and 52 are amended herein. Claims 1-26, 28, 30, 34, 41-43, 45-47, 53, 55, 65, 66 and 68-70 were previously cancelled without prejudice or disclaimer as to the subject matter of the cancelled claims. Applicant respectfully reserves the right to prosecute the subject matter of the cancelled claims in one or more continuation or divisional applications.

**Substance of Interview Pursuant to 37 C.F.R. § 1.133(b)**

In accordance with 37 C.F.R. § 1.133(b) and M.P.E.P. § 713.04, Applicant provides a summary of the telephonic interview of December 11, 2008. Applicant appreciates the courtesies extended by the Examiner during the interview. During the interview, the undersigned and Pierre Kary, PhD, representative of the Applicant and Assignee company, discussed proposed changes to both independent claims 27 and 52, intended to overcome the outstanding indefiniteness rejection with respect to the alleged inconsistent or ambiguous use of “consisting essentially of” and “comprising” phraseology. In particular the rewording of both independent claims to delete the “consisting essentially of” claim phraseology from the preamble thereof, and reinserting said phraseology at the end of the claim, the incorporation of the recitation to make clear in the preamble that the claimed endoprosthesis is “injectable into soft tissue as a polymer hydrogel” as well as the rephrasing (revised order) of certain clauses in these claims so that the claims read better in view of the prior mentioned revisions was discussed. In addition, Applicant’s representatives discussed where support for the proposed changes to the claims could be found in the as-filed application. This amendment formally presents the discussed claim revisions.

During the interview, the Examiner indicated that in his view these revisions would appear to overcome the outstanding indefiniteness rejection and that the claim changes would be entered upon formal submission notwithstanding the status of the rejection (final). However the Examiner indicated that these amendments upon formal submission would be brought to the attention of the QAS for further review, and that if found deficient that the Patent Office would suggest alternative language especially as this indefiniteness rejection is the only outstanding

issue precluding allowance of this application (which has been pending over 7 years). The Examiner is again thanked for his helpful advice during the interview.

### **Withdrawn Rejections**

Applicant appreciates the Examiner's withdrawal of the prior rejection under the judicially created doctrine of obviousness-type double patenting based on the Terminal Disclaimer submitted with Applicant's previous response.

### **Rejections**

#### *Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph*

Claims 27, 29, 31, 33, 35-40, 44, 48-52, 54, 56-64, 67 and 71-76 were rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention by the Applicant.

Applicant respectfully disagrees and traverses this rejection.

The Office Action states that “[t]he claims are indefinite in that the ‘comprising language’ is found in the claims after ‘consisting essentially of’ language has been used.” *See* Office Action, page 3. Applicant respectfully disagrees for the reasons of record. However, in any event it is believed that this rejection should be overcome based on the amendment of claims 27 and 52 herein. It is Applicant’s understanding based on - the recent interview that the amendments of claims 27 and 52 should render this rejection moot.

In particular Applicant notes that both independent claims have been amended to delete the “consisting essentially of” phraseology in the claim preamble and reinserting said phraseology at the end of the claim, and further now recites that the endoprosthesis is “injectable into soft tissue as a polymer hydrogel” and the order of certain clauses has been reworded based on these changes. With the possible exception of the deleted “consisting essentially of” language and the inserted phrase “endoprosthesis “being injected into soft tissue as a polymer hydrogel” the other changes to the claims merely revise the order of certain phrases and are not believed to raise any issues of new matter.

Specific explicit or implicit support for the added phrase as to the endoprosthesis “being injected into soft tissue as a polymer hydrogel” may be found at least in the following sections of the as-filed specification:

Page 2, line 21 “the invention relates to a hydrogel for use as a soft tissue filler”

Page 2, lines 28-30, “the invention relates to the use of a hydrogel comprising less than 3.5% by weight polyacrylamide, based on the total weight of the hydrogel, for the preparation of an endoprosthesis for soft tissue filling”

Page 3, lines 31-33, “The present investigators have prepared a hydrogel having the desired theological properties to act as a soft tissue filler endoprosthesis”

Page 4, line 5, The invention relates to a hydrogel for use as a soft tissue filler endoprosthesis”

Page 5, line 30, “Upon administration of the hydrogel, a thin layer of connective tissue surrounds the endoprosthesis”

Page 6, lines 10-11, “ The hydrogel of the invention is typically for use as an injectable endoprosthesis”

Page 5, lines 15-16, “The hydrogel of the invention may be injectable or implantable into the subcutaneous region of the epidermis”

Page 8, lines 8-9, “the method of the invention typically comprises administering the hydrogel of the invention by injecting the hydrogel into the subcutaneous layer of the skin”

Page 15, Example 2, “The injection of the gel may be under local anesthesia”.

As discussed at the recent interview, in order to expedite prosecution and render moot the 112 rejection, the “consisting essentially of “ clause in the preamble of both independent claims has been deleted. As further discussed at the interview the deleted phrase is not required in the preamble as the amended claims both recite that the endoprosthesis “[is] injectable into soft

tissue as a polymer hydrogel". This clearly articulates the fact that in the present invention the hydrogel itself is injected into soft tissue wherein it functions as a soft tissue filler.

For completeness, and as mentioned *supra*, the remaining claim changes are formal in nature and specific support for the recitations may be found in Applicant's previous replies, incorporated by reference herein.

It is anticipated based on the recent interview that these changes should obviate the outstanding indefiniteness issues as the claims are not ambiguous in their metes and bounds.

In particular, the current claims make clear that a hydrogel possessing the very specific rheological properties recited in the claim and further comprising very specific crosslinked polymers and monomer content is being claimed or its use as an endoprosthesis whereby it is administered such as via injection at a site whereby given these novel properties and composition it functions as a stable tissue filler (endoprosthesis). Accordingly, a skilled artisan reading the claims would readily understand the specific novel and non-obvious properties of the recited hydrogel endoprosthesis as well as its claimed use for soft tissue augmentation.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of claims 27, 29, 31, 33, 35-40, 44, 48-52, 54, 56-64, 67 and 71-76 under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph.

## CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

In the event any outstanding issues remain, Applicant would appreciate the courtesy of a telephone call to Applicant's undersigned representative to resolve such issues in an expeditious manner.

It is believed that no fees are due with the filing of this Response. However, if the U.S. Patent and Trademark Office determines that any variance exists between the amount due and the amount authorized above, the Commissioner is authorized to credit or debit any such variance to the undersigned's Deposit Account No. **50-0206**.

Respectfully submitted,

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